

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

AMICUS THERAPEUTICS US, LLC AND
AMICUS THERAPEUTICS, INC.,

Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC.; and
TEVA PHARMACEUTICALS, INC,

Defendants.

C.A. No. 22-1461-CJB
ANDA CASE

Consolidated

**CONSENT JUDGMENT AND PERMANENT INJUNCTION AS TO TEVA
PHARMACEUTICALS USA, INC. AND TEVA PHARMACEUTICALS, INC.**

This matter is before the Court on the unopposed motion of Plaintiffs Amicus Therapeutics US, LLC and Amicus Therapeutics, Inc. (collectively “Amicus”) and Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals, Inc. (collectively “Teva”).

WHEREAS, Amicus owns U.S. Patent Nos. 9,987,263; 10,383,864; 11,633,388; 11,833,164; 12,042,489; and 12,042,490 (“the Asserted Patents”);

WHEREAS, Teva submitted Abbreviated New Drug Application No. 217586 (“Teva’s ANDA”) to the FDA under 21 U.S.C. § 355(j) seeking to obtain approval to commercially manufacture and sell generic migalastat for treatment of Fabry disease;

WHEREAS, in this Action, Amicus alleges that Teva infringed one or more claims of the Asserted Patents under 35 U.S.C. § 271(e)(2) by virtue of Teva’s submission of Teva’s ANDA to the FDA;

WHEREAS, in this Action, Amicus alleges that it would be irreparably harmed if Teva were not enjoined from infringing or actively inducing or contributing to infringement of one or

more claims of the Asserted Patents;

WHEREAS, in this Action, Amicus requested that this Court enter a permanent injunction enjoining Teva from infringing the Asserted Patents;

WHEREAS, in this Action, Teva has denied that the Asserted Patents are valid, enforceable, and infringed by the product described in Teva's ANDA;

WHEREAS, Amicus and Teva have reached an agreement to finally settle the Litigation as set forth in this Consent Judgment and Permanent Injunction as to Teva and a separate License Agreement ("License Agreement") which is contemporaneously and separately being executed;

WHEREAS, final settlement of this Action will help Amicus and Teva avoid the substantial uncertainty and risks involved with prolonged litigation;

WHEREAS, final settlement of this Action will permit Amicus and Teva to save litigation costs, as well as adhere to the judicially recognized mandate that encourages the settlement of litigation whenever possible;

WHEREAS, final settlement of the Action serves the public interest by saving judicial resources and avoiding the risks to each of Amicus and Teva associated with infringement; and

WHEREAS, Amicus and Teva each consent to personal jurisdiction in Delaware for purposes of enforcing the License Agreement;

IT IS HEREBY ORDERED, DECREED, and ADJUDGED as follows:

1. The Court has jurisdiction over Amicus and Teva and the subject matter of this litigation.
2. Teva acknowledges Amicus's ownership and standing to sue for infringement of the Asserted Patents.
3. Teva acknowledges that the Asserted Patents are valid and enforceable, as described more fully and subject to the restrictions contained in the License Agreement.

4. Teva acknowledges that it has infringed the Asserted Patents under 35 U.S.C. § 271(e)(2) and that Amicus did not authorize the manufacture, use, sale, offer for sale, importation and distribution of the product described in Teva's ANDA.

5. Teva and its successors, assigns, and affiliates, and partners or joint-venturers with are permanently enjoined as of the date hereof from infringing the asserted patents by the commercial manufacture, use, offer to sell, sale, importation, or distribution of any generic migalastat products that are the subject of Teva's ANDA that is not pursuant to a license granted by Amicus or otherwise exempt from infringement under 35 U.S.C. § 271(e)(1), and from inducing others to infringe or contributing to the infringement of the asserted patents by inducing others to manufacture, use, offer to sell, sale, import, or distribute or contributing to others' manufacture, use, offer for sale, sale, importation, or distribution of any generic migalastat products that are the subject of Teva's ANDA that is not pursuant to a license granted by Amicus or otherwise exempt from infringement under 35 U.S.C. § 271(e)(1).

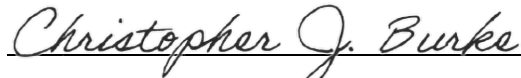
6. All claims in this Action against Teva are hereby dismissed without prejudice.

7. Each party shall bear its own costs and attorneys' fees.

8. This Court shall retain jurisdiction over Teva and Amicus for the purpose of enforcing the terms of this Consent Judgment and Permanent Injunction and over any matters related to or arising from the interpretation or enforcement of the License Agreement or any legal or equitable claim concerning the License Agreement by any third party.

9. This Consent Judgment constitutes a "consent decree" pursuant to 21 U.S.C. § 355(j)(5)(B)(iii)(I)(bb), such that Final Approval of Teva's Abbreviated New Drug Application No. 217586 under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) may be granted on the date that this Consent Judgment is entered.

IT IS SO ORDERED, DECREED AND ADJUDGED this 24th day of October, 2024 by:



The Honorable Christopher J. Burke
United States Magistrate Judge

Dated: October 17, 2024

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